

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PharmacyChecker.com LLC,

Plaintiff,

v.

National Association of Boards of Pharmacy,
Alliance for Safe Online Pharmacies, Center
for Safe Internet Pharmacies Ltd., LegitScript
LLC, and Partnership for Safe Medicines,
Inc.,

Defendants.

Civil Action No.: 7:19-cv-07577-KMK

DEFENDANT NATIONAL ASSOCIATION
OF BOARDS OF PHARMACY'S BRIEF IN
OPPOSITION TO PLAINTIFF'S MOTION
FOR PRELIMINARY INJUNCTION

Judge Kenneth M. Karas

Magistrate Judge Paul E. Davison

Dated: August 30, 2019

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I. PRELIMINARY STATEMENT

Plaintiff PharmacyChecker.com LLC filed its Complaint and its Notice of Motion and Motion for Preliminary Injunction and supporting brief as part of a concerted, multi-pronged effort to appeal to the false but popular consumer belief that they can legally and safely save money by buying drugs from Canadian pharmacies. DE 1 (Compl), 15-20, 33 (Corrected Br.). In addition to filing this lawsuit, PharmacyChecker has drafted press releases, blog posts, and web postings, all advocating that Americans should be allowed to import pharmaceuticals from foreign pharmacies, particularly those that appear to be in Canada, because prices for those pharmaceuticals at least appear to be less expensive than comparable medicine sold in American pharmacies. *See* Declaration of Paul Olszowka (“Olszowka Decl.”), **Exh. E, K, and L**.

Lost in that advocacy, or at least substantially downplayed, is one undisputed fact – it is illegal. Federal law, and most states’ law, prohibit businesses and individuals from engaging in, or facilitating, the importation of pharmaceuticals from other countries into the United States. It is a felony which, when charged, can subject the foreign pharmacy, the American consumer, and those that facilitate these transactions to significant criminal and civil penalties. *See* 21 U.S.C. §§331, 333, 381(d), 384; 18 U.S.C. §§545, 371. Plaintiff admits that the conduct it advocates, and what Plaintiff seeks an injunction to facilitate, has long violated federal law.¹ *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 788-89 (8th Cir. 2006) (FDA “repeatedly has expressed the view that virtually all importation of drugs into the United States by individual consumers violates the [Federal Food, Drug, and Cosmetic Act (“FDCA”)], because the drugs are not approved in accordance with 21 U.S.C. §355, are not labeled as required by 21 U.S.C.

¹ Olszowka Decl., **Exh. J** (“Is it legal to import medication that you order online? Answer: Technically, in the U.S., no.”); **Exh. C** at 16 (“Personal Drug Imports Are Generally Permitted But Not Technically Legal”); **Exh. D** (“If you are considering purchasing medication from outside the U.S., be aware that, in most circumstances, it is technically not legal for individuals to import prescription drugs.”).

§352, or are dispensed without a valid prescription in contravention of 21 U.S.C. §353(b)(1).”); *id.* at 791 (“the importation of drugs from Canada is prohibited by federal law.”).²

It is FDA’s position “that virtually all drugs imported to the U.S. from Canada by or for individual U.S. consumers also violate[s] U.S. law” and routinely sends “Internet Pharmacy Warning Letters” to “[r]ogue online pharmacies [that] offer potentially dangerous prescription drugs to U.S. consumers” informing them that they are violating the FDCA by “offering for sale unapproved prescription drugs of unknown origin, safety, and effectiveness.” Olszowka Decl., **Exh. Q** (FDA Letter); **Exh. T** (FDA Internet Pharmacy Warning Letters). It also publishes these online to warn the public. Olszowka Decl., **Exh. T**.

Other federal agencies and officials concur. *Id.*, **Exh. U** at 6 (GAO Report stating that foreign “Internet pharmacy operators ... that cause drugs to be misbranded, adulterated, or counterfeited, as well as those that sell such drugs, violate the FDCA and are subject to enforcement action.”); **Ex. O** (“no effective way” to ensure that drugs coming from Canada really come from Canada according to current Health and Human Services (“HHS”) Secretary).

Congress repeatedly has made the considered policy judgment that the FDCA is meant to “create a ‘closed system’ designed to guarantee safe and effective drugs for consumers in the United States.” *Canadian Import*, 470 F.3d at 790; *Vermont v. Leavitt*, 405 F. Supp.2d 466, 474 (D. Vt. 2005). In the Complaint and Brief, Plaintiff posits an alternate universe where the conduct it promotes does not violate federal law. *See, e.g.*, DE 1, ¶¶48-49 (“That assertion – that prescription medicine importation is illegal – is not true.”). However, despite Plaintiff’s

² *See also Oullette v. Mills*, 91 F.Supp.3d 1, 5-11 (D. Me. 2015) (recognizing “clear Congressional intent to tightly control prescription drug importation”); *United States v. RxDepot, Inc.*, 290 F.Supp.2d 1238 (N.D. Okla. 2003) (“defendants violate 21 U.S.C. §331 by causing the importation of prescription drugs from Canadian pharmacies.”); *Vermont v. Leavitt*, 405 F. Supp.2d 466, 474 (D. Vt. 2005) (“There is no question that Vermont’s proposed program [to allow individual importation of prescription medication from Canadian pharmacies] would violate the FDCA.”).

allegations to the contrary, the federal and state laws continue to prohibit the importation of prescription drugs. Accordingly, Plaintiff's Motion for injunctive relief in circumvention of these laws should be denied; and its Complaint should ultimately be dismissed.

Plaintiff seeks extraordinary, affirmative relief against National Association of Boards of Pharmacy ("NABP") that arises from its disagreement with the current federal and state regulatory regime for which PharmacyChecker now seeks to blame NABP. Yet in making this request, Plaintiff essentially ignores the requirements for a mandatory preliminary injunction, including the Court's consideration of the substantial potential harm to NABP, the pharmaceutical drug supply, and patients.

Neither has Plaintiff shown the clear likelihood of success under Section 1 of the Sherman Act, 15 U.S.C. §1 needed for a mandatory injunction, including that Plaintiff cannot establish an "antitrust injury," and additionally, the allegations of an agreement within the Complaint do not satisfy the *Twombly/Iqbal* framework. Plaintiff's Motion should be denied.

II. PROCEDURAL HISTORY

Plaintiff filed its Complaint on August 14, 2019. DE 1. The Complaint alleges one claim, *i.e.*, that NABP, and the four other Defendants, violated Section 1 of the Sherman Act by "engaging in a scheme to suppress competition in the markets for online pharmacy verification services and comparative drug price and pharmacy information." DE 1, ¶93. Defendants allegedly did this via a "coordinated campaign designed to exclude PharmacyChecker.com and other similarly situated competitors from the market and otherwise competitively disadvantage it in the relevant markets"³ as part of a "broader goal to restrain international competition in the

³ On the other hand, PharmacyChecker.com also alleges that its "online pharmacy verification services are unique compared to its competitors" because "LegitScript and NABP do not provide any information to American consumers about safe international pharmacies that sell in the United States, and instead only provide information

market for prescription medications,” and “allocate for themselves certain geographic markets, such as the United States, Canada, and Australia.” *Id.* Plaintiff claims that “LegitScript and NABP are direct competitors of PharmacyChecker.com in that each provide online pharmacy verification services,” so “the conspiracy is a horizontal group boycott.” *Id.*, ¶94.

Plaintiff’s request for immediate injunctive relief arises from actions that took place almost eight months ago when PharmacyChecker and its blog were placed on NABP’s “Not Recommended Sites.” *Id.*, ¶¶78, 81; Declaration of Carmen Catizone (“Catizone Decl.”), ¶¶40-41. This placement occurred on December 28, 2018 and NABP notified Plaintiff that day. *Id.*

The Section 1 claim is pled against all Defendants, but Plaintiff’s preliminary injunction motion is directed only at NABP and Center for Safe Internet Pharmacies Ltd. (“CSIP”). According to the Complaint, CSIP’s members *do not* include NABP but do include various “internet commerce gatekeepers,” like Google, Microsoft, Facebook, and others. DE 1, ¶8. According to Plaintiff, “[a] main purpose of CSIP” is to “obtain consensus from these gatekeepers to create new barriers to Internet commerce that would otherwise mean open competition in the markets relating to prescription drugs.” *Id.*

As to NABP, Plaintiff asks this Court now to: (1) NABP change its websites and remove PharmacyChecker from NABP’s Not Recommended Sites List (which has been in place for about eight months) and (2) inform anyone who has used the list of that fact. DE 16, 2.

III. STATEMENT OF FACTS

A. What NABP Does.

NABP was founded in 1904 to establish interstate licensure transfer for pharmacists based upon uniform educational standards. NABP is a private, non-profit organization that

about U.S.-based online pharmacy websites.” DE 1, ¶32. Plaintiff also does not allege that NABP is a competitor of its in providing “comparative drug pricing information.” *Id.*, ¶33.

provides educational and accreditation services to support its member state boards of pharmacy and protect public health. Catizone Decl., ¶¶3-5. It assesses pharmacists' competence, and accredits or verifies pharmacists, pharmacies, wholesale distributors of drugs, among others, as part of its mission to protect public health. *Id.*, ¶¶6-11. Its members are 65 domestic and international boards of pharmacy, from all fifty United States, the District of Columbia, Guam, Puerto Rico, the U.S. Virgin Islands, ten Canadian provinces, and Bahamas. *Id.*, ¶12. It receives most of its funding from its accreditation and testing services. *Id.*, ¶14. The Association receives no operationally supporting funding from pharmaceutical companies. *Id.*

B. The VIPPS Program And Not Recommended Sites List.

In 1999, NABP established the Verified Internet Pharmacy Practice Sites ("VIPPS") program to protect the nation's drug and device supply chain and distribution system from counterfeit and diverted products by verifying and accrediting Internet websites offering pharmacy services. *Id.*, ¶21. Under the VIPPS program, NABP accredits U.S. pharmacies only that, based on NABP's review of the pharmacy's website, procedures, etc., comply with federal and state law and industry best practices. *Id.*, ¶¶21-25. Over 15,000 licensed pharmacies nationwide, are now VIPPS-accredited. *Id.*, ¶25.

Since 2008, NABP has also published on its website its "Not Recommended Sites" list (the NRL). *Id.*, ¶¶31-32. That list identifies websites that appear to violate federal or state law or best practices because they "dispense prescription medicine without a prescription," "[d]ispense foreign or unapproved medicine," or "[r]efer/link patients to sites that facilitate the dispensing of prescription medications in violation of state or federal law or NABP standards." *Id.*, ¶33.

C. The Prescription Drug Regulatory Regime.

The FDA heavily regulates prescription drugs in the United States, principally through the FDCA. 21 U.S.C. § 301, *et. seq.* Drugs that qualify as “controlled substances” are further regulated by the Drug Enforcement Administration (DEA). 21 U.S.C. § 801, *et. seq.* This includes regulations relating to the importation of prescription drugs. Importing means introducing a drug from outside the United States into the United States. 21 U.S.C. § 355(b)(1).

Through the FDCA, Congress has “create[d] a ‘closed system’ designed to guarantee safe and effective drugs for consumers in the United States.” *Canadian Import*, 470 F.3d at 790; *Leavitt*, 405 F. Supp.2d at 473. The FDCA prohibits the interstate shipment (including importation) of “unapproved new drugs,” which include drugs, including foreign-made versions of U.S. approved drugs, not manufactured in accordance with and pursuant to strict FDA approval. 21 U.S.C. § 355(a). FDA approval is manufacturer and product specific, including any foreign version of a drug. 21 C.F.R. §314.50. Obtaining FDA approval is an extensive process requiring a manufacturer to submit information establishing a drug’s safety and efficacy, and information about the method, facilities, and manner of manufacture. 21 U.S.C. § 355(b)(1). If not specifically FDA approved, the imported drug is considered “misbranded” which subjects all involved in its importation to potential criminal penalty, including fines and imprisonment. 21 U.S.C. §§ 333, 352. A drug is also “misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol ‘Rx only.’” 21 U.S.C. §353(b)(4)(A). Canadian drugs do not have such a label. *Canadian Import*, 470 F.3d at 789.

The FDA states that “[i]f you buy drugs that come from outside the U.S., the FDA doesn’t know what you’re getting, which means safety can’t be assured. ... With an unapproved drug, you can’t be sure that it has been shipped, handled, and stored under conditions that meet U.S. requirements.” Olszowka Decl., **Exh. S** at 2 (*Imported Drugs Raise Safety Concerns*); **Exh.**

Q at 2 (“virtually all drugs imported to the U.S. from Canada by or for individual U.S. consumers also violate U.S. law.”).

The FDCA also prohibits re-importing (re-introducing into the United States) an FDA-approved drug by anyone other than the manufacturer of the drug. 21 U.S.C. §381(d)(1). If a drug was lawfully manufactured in the United States, and then exported to a foreign country, it is illegal for anyone but the FDA-approved manufacturer to re-introduce the drug into this country. 21 U.S.C. §§331(t), 333. According to the FDA, once a product has been exported, it is unable to guarantee its safety and therefore importation of the drug is prohibited unless performed by the drug manufacturer. 21 U.S.C. §381(d); Olszowka Decl., **Exh. S** at 3.

The per occurrence penalty for unlawful importing applies to the importer and all those involved in organizing, aiding and abetting, facilitating, or causing the importation, including the subsequent distribution and dispensing of the drug. 18 U.S.C. §§2, 333, 371, 545. If the importation was committed with intent to defraud or mislead, it may be charged as a felony with up to three years imprisonment and a \$250,000 fine. 21 U.S.C. §333(a)(2); 18 U.S.C. §3571. Otherwise, it is typically a strict liability misdemeanor with up to one year imprisonment and a \$100,000 fine. 21 U.S.C. §333(a)(1); 18 U.S.C. §3571. If the offense involved knowing importation of a prescription drug originally manufactured in the United States, it is punishable by up to 10 years imprisonment and a \$250,000 fine. 21 U.S.C. §333(b)(1)(A). The penalties are even more severe if controlled substances are involved. 21 U.S.C. §960(b)(5-7).

D. FDA Guidance on the Importation of Prescription Drugs.

The FDA has published lengthy guidance that addresses the laws and other issues regarding the personal importation of drugs from Canada, which says, in part (emphasis added):

The [FDCA or] (Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act. Unapproved new drugs are any drugs, including

foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval. Under the Act, FDA may refuse admission to any drug that "appears" to be unapproved, placing the burden on the importer to prove that the drug sought to be imported is in fact approved by FDA. Absent evidence that the specific drugs sought to be imported from a foreign country/area have been manufactured pursuant to an approved new drug application, in the manufacturing facility permitted under the application, such drugs would appear to be unapproved new drugs subject to FDA enforcement action. ...

The guidance document is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S., and even if all the factors noted in the guidance are present, the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized. Similarly, the factors noted in the guidance, and documentation that should be obtained from individuals importing the drugs, are not mandatory requirements. They are intended to guide FDA enforcement discretion and should not be represented as binding requirements. **The statements in the RPM are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.** ...

It must be emphasized that the intent of the personal use importation guidance is to save FDA resources and to generally permit, through the exercise of enforcement discretion, medical treatments sought by individuals that are not otherwise available in the United States (where such treatments are not promoted/commercialized in the U.S.). **Thus, foreign-made chemical versions of drugs available in the U.S. are not intended to be covered by the policy.** For example, a person may decide that his or her FDA approved heart medication is cheaper in Mexico, and attempt to import the unapproved version of the drug from Mexico. FDA cannot assure that such products have been properly manufactured and are effective; therefore, given that such products are available in the U.S., their use would present an unreasonable risk and the guidance would not apply (unless the person seeking their importation could establish that the drugs were needed to refill a prescription while traveling or were otherwise needed while traveling). ...

[A] foreign-made version of the U.S. approved drug would not generally be considered a candidate to be permitted entry under the guidance. ...

Congress has the power to determine which articles may be permitted importation into the United States from a foreign source and the terms upon which the importation will occur. **An article subject to the Federal Food, Drug, and Cosmetic Act is still in "interstate commerce" even if it is purchased before being shipped across state lines. This is true even if the article is intended solely for personal consumption. Therefore, the Act properly regulates personal articles imported into the United States for personal consumption.**

The Act also prohibits the importation into the United States of any unapproved new drug. ...

We appreciate that there is a significant cost differential between drugs available here and those in other countries/areas. However, **many drugs sold in foreign countries/areas as "foreign versions" of approved prescription drugs sold in the United States are often of unknown quality with inadequate directions for use and may pose a risk to the patient's health.** FDA approves a drug on the basis of scientific data proving it to be safe and effective. FDA approved labeling provides information on how and when the drug can be used to maximize effectiveness and minimize any harmful side effects. The manufacturing facilities and procedures for approved products are also carefully regulated by FDA to ensure product integrity. **Since FDA cannot assure the consumer that the drug purchased in the foreign country/area would be the same product his or her physician's prescription is written for, we recommend the product covered by the prescription be acquired in the United States.**

Olszowka Decl., **Exh. R.** Plaintiff links to this document on its website but essentially ignores the contents in the Complaint and Motion. *Id.*, **Exh. C.** According to Plaintiff's website, while the FDA guidance provides that importation of pharmaceuticals is "not technically legal," *id.*, the conduct rarely leads to criminal prosecution. *Id.*, **Exh. C and D.**

But as the Eighth Circuit explained in *Canadian Import*, Congress and HHS, which houses the FDA, specifically addressed personal importation of drugs from Canada.

In 2000 and 2003, Congress enacted amendments to the [FDCA] that would permit limited importation of certain prescription drugs from Canada by pharmacists, wholesalers, or individuals, 21 U.S.C. § 384(b), (j), but only if the Secretary of [HHS] first certifies that the importation would "pose no additional risk to the public's health and safety" and that it would "result in a significant reduction in the cost of covered products" for American consumers. 21 U.S.C. § 384(l). **Three Secretaries of [HHS] in the last two presidential administrations have declined to make the requisite certifications.**

That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the pre-existing system established by the FFDCA does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescriptions drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. § 384.

Canadian Import, 470 F.3d at 790-91 (citations omitted; emphasis added). And as discussed below, the Eighth Circuit ruled that consumers had no antitrust standing to challenge pharmaceutical manufacturers' alleged conspiracy to limit the personal importation of prescription drugs.

E. The Federal Government Has Taken Serious Enforcement Actions To Stop the Personal Importation of Drugs from Canada.

The Justice Department has taken very public and serious civil and criminal action against market participants who participate in, or facilitate, the illegal importation of drugs from Canada. After an eight-year investigation, in 2011, the DOJ and the FDA entered into a settlement agreement with Google which required Google to forfeit \$500 million generated by its online ads for Canadian online pharmacies which “result[ed] in the unlawful importation of controlled and non-controlled prescription drugs into the United States.” Olszowka Decl., **Exh. P** (DOJ press release); **Exh. N** (Google Non-Prosecution Agreement).⁴ According to the DOJ, “[t]he importation of prescription drugs to consumers in the United States is almost always unlawful.” *Id.*, **Exh. P**. “While Canada has its own regulatory rules for prescription drugs, Canadian pharmacies that ship prescription drugs to U.S. residents are not subject to Canadian regulatory authority, and many sell drugs obtained from countries other than Canada which lack adequate pharmacy regulations.” *Id.*⁵

⁴ The Non-Prosecution Agreement states that Google used PharmacyChecker beginning in 2006 as a verification service. According to the Agreement, Google “knowingly permitted Canadian online pharmacies, certified by PharmacyChecker, to advertise the sale of non-controlled prescription drugs through AdWords to U.S. Consumers.” *Id.*, **Exh. N** at 4. This is part of the conduct for which Google was sanctioned.

⁵ During the investigation, but before it reached its agreement with the DOJ and FDA, Google “took a number of steps to prevent the unlawful sale of prescription drugs by online pharmacies to U.S. consumers,” including “requiring online pharmacy advertisers to be certified by [NABP’s VIPPS program], which conducts site visits; has a stringent standard against the issuance of prescriptions based on online consultations; and, most significantly, does not certify Canadian online pharmacies.” *Id.*

In 2014, the DOJ indicted CanadaDrugs.com, a Canadian online pharmacy, formerly accredited by PharmacyChecker, and over ten other affiliates, entities, and individuals, for participating in the sale of \$78 million of unapproved, mislabeled and counterfeit drugs to medical practitioners in the United States. *Id.*, **Exh. V** (Docket). According to the superseding indictment, Canada Drugs’ affiliates bought non-FDA authorized or mislabeled drugs abroad, and shipped them to the United States to sell to physicians at lower prices in violation of 18 U.S.C. §§371 and 545, and 21 U.S.C. §§331(a) and (d), among others. *Id.*, **Exh. W** (Superseding Indictment). The DOJ also alleged that “Canada Drugs’ consumer operations were focused on the illegal shipment of low cost, unapproved, and misbranded prescription drugs to Americans.” *Id.*, ¶22. This indictment, and the resulting guilty pleas and dispositions, received substantial notice in the pharmaceutical industry.⁶ *Id.*, **Exh. X**.

F. NABP’s Interaction with PharmacyChecker.

In December 2018, NABP evaluated Plaintiff’s websites and concluded that they clearly meet NABP’s criteria for inclusion on its NRL because they “refer/link patients to sites that facilitate the dispensing of prescription medications in violation of state or federal law or NABP standards.” Catizone Decl., ¶¶40-48. Based on NABP’s analysis, Plaintiff’s websites referred patients to sites that violate federal law or facilitate violations when selling drugs online. *Id.* On December 28, 2018, NABP placed PharmacyChecker.com and its blog on the NRL and informed Plaintiff it had done so. *Id.*, ¶41. The same day, Plaintiff complained that NABP had done so but after a few additional e-mails thereafter did nothing further. *Id.*, ¶¶49-50.

⁶ Plaintiff obliquely references this indictment in its Complaint as an example of “false information” spread about PharmacyChecker. *See* DE 1, ¶76. NABP notes that the Complaint does not allege anything “misleading” that NABP stated, and also that, contrary to Plaintiff’s allegations, the individual related to Plaintiff was dismissed without prejudice under a deferred prosecution agreement only after any statement made by NABP. *See* Olszowka Decl., **Exh. V** (October 20, 2015 order dismissing Kamath).

As alleged in the Complaint, three months later, “PharmacyChecker.com’s site traffic from organic search results has dropped more than 78%,” and its “monthly click-through revenue has dropped by more than 72%...” DE 1, ¶98. Plaintiff alleges that Defendants’ conduct caused it to drop in the rankings for various Google searches after Google updated its search algorithms in March 2019. *Id.*, ¶¶99, 31; *compare* Olszowka Decl., **Exh. M** (“The first Google Update of 2019 has caused major upheaval in the global search results.”). Plaintiff also alleges that its traffic through Bing, Microsoft’s search engine, “vastly diminished” since July 21, 2019 because Bing has now placed a “pop-up WARNING” on searches for its website. DE 1, ¶101. Finally, Plaintiff alleges that it has lost “at least five” customers since March. DE 19, ¶21.

On June 4, 2019, Plaintiff sent NABP a letter accusing it of improperly placing its websites on the NRL and accusing NABP of anticompetitive conduct. Catizone Decl., ¶51. On June 27, 2019, NABP responded, refuting those assertions. *Id.*, ¶¶52-71. Plaintiff then waited almost two more months and has now filed this lawsuit. DE 1.

IV. ARGUMENT

A. The Standard Applicable to Plaintiff’s Request for a Mandatory, Preliminary Injunction.

A preliminary injunction is an “extraordinary and drastic remedy, one that should not be granted unless the movant, by a *clear showing*, carries the burden of persuasion.” *Sussman v. Crawford*, 488 F.3d 136, 139 (2d Cir.2007) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)); *Benisek v. Lamone*, 138 S. Ct. 1942, 1943 (2018) (“preliminary injunction is an extraordinary remedy never awarded as of right.”) (citation omitted). The burden to obtain relief on an immediate and preliminary basis is “much higher” than at summary judgment following discovery. *Mazurek*, 520 U.S. at 972. Moreover, “the court need not accept all of a plaintiff’s assertions on a motion for preliminary injunction as true.” *Burroughs v. County of Nassau*, 2014 WL 2587580, *8 (E.D.N.Y. June 9, 2014).

To obtain a preliminary injunction, a party must ordinarily establish (1) “irreparable harm”; (2) “either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party”; and (3) “that a preliminary injunction is in the public interest.” *Oneida Nation of New York v. Cuomo*, 645 F.3d 154, 164 (2d Cir.2011) (internal quotation marks omitted); *Citigroup Global Markets, Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010).

Irreparable harm is the “*sine qua non* for preliminary injunctive relief.” *USA Recycling, Inc. v. Town of Babylon*, 66 F.3d 1272, 1295 (2d Cir.1995). Irreparable harm is an “injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages.” *Forest City Daly Hous., Inc. v. Town of N. Hempstead*, 175 F.3d 144, 153 (2d Cir. 1999) (internal quotation marks omitted); *Grand River Enters. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007).

“[C]ourts must not simply presume irreparable harm.” *Salinger v. Colting*, 607 F.3d 68, 82 (2d Cir. 2010). “Rather, plaintiffs must show that, on the facts of their case, the failure to issue an injunction would actually cause irreparable harm.” *Id.* A plaintiff must show this “before the other requirements for the issuance of [a preliminary] injunction will be considered.” *Rodriguez v. DeBuono*, 175 F.3d 227, 234 (2d Cir.1998). “[P]rovable monetary damages from the loss of a profitable line of business” does not constitute irreparable harm. *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 38 (2d Cir.1995).

“Where the movant seeks a mandatory injunction (one that will alter the status quo) rather than a prohibitory injunction (one that maintains the status quo), the likelihood-of-success standard is elevated: the movant must show a clear or substantial likelihood of success.” *Hoblock v. Albany County Bd. of Elections*, 422 F.3d 77, 97 (2d Cir. 2005) (citations omitted);

Jolly v. Coughlin, 76 F.3d 468, 473 (2d Cir. 1996) (“an even higher standard applies”). A mandatory injunction “alter[s] the status quo by commanding some positive act.” *Tom Doherty Assocs., Inc.*, 60 F.3d at 33–34; *Cacchillo v. Insmmed, Inc.*, 638 F.3d 401, 406 (2d Cir. 2011).

Plaintiff seeks an immediate injunction commanding that (1) NABP change its websites and remove PharmacyChecker from NABP’s Not Recommended Sites List (which has been in place for about eight months) and (2) inform anyone who has used the list of that fact. DE 16. Plaintiff’s argument that this is not a mandatory injunction and maintains the status quo should be rejected. *Id.* at 2, 25. The “status quo” which Plaintiff seeks is the time before it was placed on the Not Recommended List – almost eight months before it filed its Complaint. *Id.* at 25.

Plaintiff’s requests are nothing like returning to the status immediately before Plaintiff filed suit. Requiring NABP to remove PharmacyChecker from the list and inform others that it has done so is also “alter[ing] the status quo by commanding some positive act.” *Tom Doherty Assocs., Inc.*, 60 F.3d at 33–34. Plaintiff can only be seeking a mandatory injunction, so the highest standard applies. *Trinity Indus., Inc. v. Chicago Bridge & Iron Co.*, 735 F.3d 131, 139 (3d Cir. 2013) (mandatory injunctions “granted sparingly” and only “in the most unusual case.”).

B. Plaintiff Has Not Even Established That This Is the Proper Venue for the Lawsuit.

Plaintiff’s allegations are meager and call into serious question whether venue is proper. Plaintiff baldly asserts that “defendants can be found in this district,” 15 U.S.C. §22, and “a substantial part of the events or omissions giving rise to this dispute occurred in this district: defendants targeted their conspiracy at PharmacyChecker.com which resides in this district.” DE 1, ¶2 (citing 28 U.S.C. §1391). Importantly, Plaintiff does not base its venue allegations on the Defendants transacting business or residing in the district.

Plaintiff allege no supporting facts suggesting that NABP “can be found in this district.” 15 U.S.C. §22. Incorporated in Kentucky, its only place of business is Mount Prospect, Illinois.

DE 1, ¶6. So, it clearly does not inhabit or “reside” here. *Id.*; 28 U.S.C. §1391(c). “Being ‘found’ in a district is generally equated with ‘doing business’ there, and requires greater contacts than does ‘transacting business.’” *In re Automotive Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 293 n.6 (3d Cir. 2004) (citing *Gen. Elec. Co. v. Bucyrus-Erie Co.*, 550 F.Supp. 1037, 1041 n.5 (S.D.N.Y. 1982)). “A corporation is ‘found’ where it has ‘presence’ and ‘continuous local activities’ in the district.” *Id.* (citing cases). Plaintiff alleges no facts suggesting that NABP has both “presence” and “continuous local activities” in this district. The fact that, while unalleged, the New York State Board of Pharmacy is a member of NABP does not impact this inquiry because NABP “does not control” the New York Board. *Friends of Animals, Inc. v. American Veterinarian Med. Ass’n*, 310 F.Supp. 620, 624 (S.D.N.Y. 1970).

The same is true for the other Defendants, some of whom have not even entered their appearance yet. No Defendant is incorporated or has its principal place of business here. DE 1, ¶¶7-10 (organized and principal places of business in D.C., Delaware, California or Oregon). Nothing alleged suggests that any of the Defendants “can be found” here. 15 U.S.C. §22.

Indeed, the entire Complaint curiously lacks any geographic connection to any particular venue. No agreements or meetings or contracts or anything are alleged to have taken place in New York.⁷ Certainly, nothing suggests that “a substantial part of the events or omissions giving rise to the claim occurred” in this district. 28 U.S.C. §1391(b).⁸ Here, *no* events or omissions allegedly occurred in this district. The Second Circuit has found a lack of venue with many more “events or omission in the forum” than alleged here. *Daniel*, 428 F.3d at 432-33.

⁷ Indeed, if there is any central place for the alleged conduct, it is Illinois or the District of Columbia.

⁸ “‘Substantiality’ for venue purposes is more a qualitative than a quantitative inquiry, determined by assessing the overall nature of the plaintiff’s claims and the nature of the specific events or omissions in the forum, and not by simply adding up the number of contacts.” *Daniel v. American Bd. of Emergency Medicine*, 428 F.3d 408, 432-33 (2d Cir. 2005).

The real likelihood that this may be an improper venue to litigate this matter counsels against any decision that could address the merits before the propriety of this venue is addressed with all Defendants.

C. PharmacyChecker Has Not Alleged Any Imminent Irreparable Harm Caused By NABP.

Plaintiff has not adequately alleged that NABP has caused, or will cause it, irreparable harm. In fact, Plaintiff's own allegations refute its irreparable harm claim.

1. Plaintiff Delayed Almost Eight Months After NABP Placed It On Its "Not Recommended Sites" List Before Filing Its Complaint.

NABP informed Plaintiff that it had put PharmacyChecker.com on its "Not Recommended Sites" list on or about December 28, 2018. Catizone Decl., ¶41. PharmacyChecker.com responded the very same day, acknowledging that it was aware that it had been placed on the list. *Id.*, ¶49. After learning it was on the list in December 28, 2018, Plaintiff then apparently did nothing for close to six months until it finally sent NABP a demand letter on June 4, 2019. *Id.*, ¶51. NABP responded to that letter on June 27, 2019, explaining why Plaintiff's assertions were false and not actionable. *Id.*, ¶¶52-71. Plaintiff did not respond to that correspondence and instead waited almost another two months before filing its Complaint and seeking preliminary injunctive relief. DE 1, 16.

This almost eight month delay from the last action taken by NABP that Plaintiff complains about shows that this case does not merit preliminary injunctive relief. "A delay of about three months undercuts a showing of immediate and irreparable injury." *Livery Round Table, Inc. v. New York City FHV and Limousine Comm'n*, 2018 WL 1890520, *9 (S.D.N.Y. April 18, 2018) (denying preliminary injunction) (citing *Ins. Co. of the State of Pa. v. Lakeshore Toltest JV, LLC*, 2015 WL 8488579, *3 (S.D.N.Y. Nov. 30, 2015) ("Delay [in bringing a preliminary injunction motion] ... 'indicates an absence of the kind of irreparable harm required

to support a preliminary injunction.”) (quoting *Citibank, N.A. v. Citytrust*, 756 F.2d 273, 276 (2d Cir. 1985)); *Carson Optical, Inc. v. Alista Corp.*, 2019 WL 3729460, *5 (Aug. 8, 2019) (less than three month delay “suggest[] a lack of irreparable harm”) (citing cases).

Here, Plaintiff delayed almost eight months from the time it learned it had been placed on the Not Recommended Sites List. Plaintiff’s Motion should be denied on this ground alone.

2. Nothing NABP Did Has Caused Plaintiff Injury Or Irreparable Harm.

Plaintiff’s own allegations confirm that NABP did not cause it irreparable harm. Although Plaintiff was placed on the Not Recommended List on December 28, 2018, Catizone Decl., ¶41, that action did not cause *anything* to happen to Plaintiff. In fact, Plaintiff does not point to any evidence of its web traffic before being placed on the NRL, and even uses the period *after* that to demonstrate Plaintiff’s position *before* it was allegedly harmed. See DE 15-2, ¶19 (March 11, 2019 as starting point for decline in traffic), ¶20 (period “[f]rom January to March 11, 2019” is period before it was harmed), ¶21 (revenue from February 2019 as the “before” revenue). Plaintiff’s own evidence actually shows that organic traffic *increased* from about 7,000 on January 1, 2019 (*i.e.*, after placement on the NRL) to close to 13,666 on March 11, 2019. DE 15-11. In February 2019, it was the #1 ranked search result for “online pharmacies.” *Id.*

What Plaintiff complains about is that it has lost traffic and revenue “in just the last few months,” Brief at 23, but that is months after NABP placed it on the NRL in December of 2018. In fact, in January 2019, the month after it was placed on the NRL, PharmacyChecker.com had its best month ever in gross revenue. DE 15-11. The fact that the conduct Plaintiff complains of, and wants reversed via preliminary injunction, is not causally connected to the harm it alleges, is fatal to its request for preliminary injunctive relief. *Perfect 10, Inc. v. Google, Inc.*, 653 F.3d 976, 982 (9th Cir. 2011) (“sufficient causal connection between irreparable harm” and conduct to

be enjoined is “necessary requirement for obtaining preliminary injunctive relief”).

Furthermore, Plaintiff’s assertion that it has lost revenue and customers, and “it is likely that its traffic and revenue will continue to drop as this litigation proceeds” is both speculative and conclusory. DE 33 at 23; *Forest City Daly Hous.*, 175 F.3d at 153 (irreparable harm is “injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages.”). Plaintiff complains that its ranking in Google search results declined (from top 3 to 90 for “online pharmacies”), but those rankings are transitory and vary with time, search terms, and other factors. Just yesterday, a Google search for “online pharmacy” resulted in a 19th place ranking among non-paid results.⁹

Plaintiff certainly does not show how it could not be “remedied by an award of monetary damages” at the conclusion of this litigation. *Forest City Daly Hous.*, 175 F.3d at 153. In fact, its ability to quantify its decline in monthly revenue, from \$257,796 in February to \$72,839.36 in July, DE 15-2, ¶21, shows its damages are quantifiable and so remediable by money damages.

Plaintiff states it earns income at least five different ways. DE 15-2, ¶11. However, it only discusses the effect NABP’s actions allegedly have on one way of generating revenue. *Id.*, ¶¶19-22. Plaintiff never alleges that it is actually losing money or that its expenses exceed its revenues. It simply complains about its reduction in “click-through revenue.” *Id.*, ¶21.¹⁰

⁹ A Google search for “canadian online pharmacy” yielded a 34th place ranking, behind five “Canadian” online pharmacies linked to by PharmacyChecker’s own site (OnlinePharmaciesCanada.com, Advpharmacy.com, qualityprescriptiondrugs.com, medsengage.com, and planetdrugsdirect.com). Olszowka Decl., **Exh. A, I**. Most of these are independently on the NRL too. This highlights that this suit addresses injury to a competitor, not to competition, and so is not an “antitrust injury.” *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977); *Mahmud v. Kaufmann*, 607 F.Supp.2d 541, 554 (S.D.N.Y.) (plaintiff must show “injury to competition; demonstrating injury only to individual competitors is insufficient”), *aff’d*, 358 F. App’x 229 (2d Cir.2009).

¹⁰ If its receipt of a “click-through fee for web users that click-through to a listed pharmacy” is really its “primary source of revenue,” *id.*, ¶¶11, 19, this simply confirms that this site’s primary purpose is to “refer/link patients to sites that facilitate the dispensing of prescription medications in violation of state or federal law or NABP standards,” which is one criterion for placement on the Not Recommended Sites list since the sites Plaintiff links to essentially all operate in ways that facilitate the violation of federal law. *See* Catizone Decl., ¶¶33, 41-48.

Plaintiff also claims that it has “lost at least five participants” in its various programs since March. *Id.* However, Plaintiff does not say whether it has gained any participants during that time; and, according to its website, it appears to still have at least 25 participating pharmacies. Olszowka Decl., **Exh. I**. Losing potentially five customers out of thirty (16.67%) is hardly a sufficient showing of irreparable harm. *Lanvin Inc. v. Colonia, Inc.*, 739 F.Supp. 182, 193 (S.D.N.Y. 1990) (“[c]onclusory statements,” particularly where “the allegations of irreparable harm through loss of customers is asserted only by the movant itself” is insufficient to show irreparable harm). Plaintiff’s participants also vary significantly over time. In July 2016, it had 32 participants, July 2017, it had 38, and December 2018, 31. Olszowka Decl., **Exh. F, G, H**.

“[I]ssuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with [the Supreme Court’s] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008).

D. The Harm To NABP And Patients Weighs Against An Injunction.

The balance of equities must also tip in Plaintiff’s favor. *Benisek*, 138 S. Ct. at 1943. Plaintiff’s cursory argument on this issue rests primarily on its inaccurate assertion that it seeks merely to maintain the status quo. Brief at 25. In reality, the equities favor NABP, but Plaintiff does not mention or evaluate the harm to NABP or patients an injunction would cause. Plaintiff’s delay also weighs against the equities tipping in its favor. *Benisek*, 138 S. Ct. at 1944.

1. Plaintiff Has Not Even Acknowledged The Harm To NABP And Patients.

Plaintiff entirely ignores the harm to NABP and patients from the mandatory injunction Plaintiff proposes. NABP is harmed, and, more importantly, patients’ (consumers of pharmaceuticals) health would be jeopardized, by taking Plaintiff off the NRL. Catizone Decl., ¶¶77-84. Plaintiff ignores these harms.

E. A Mandatory Injunction Places The Public At Risk

Plaintiff also cannot show that the requested relief is in the public interest. It asserts that relief must be in the public interest once a likelihood of success on the merits is found. DE 33, 24-25. That argument rests on a false premise because Plaintiff cannot show likelihood of success on his Section 1 claim. Moreover, promoting illegal conduct is hardly “in the public interest.” Finally, Plaintiff also ignores the very real threat to public health, articulated above, if the Court mandated that NABP must remove sites from its NRL. *See, e.g., City of Harrisonville, Mo. v. W. S. Dickey Clay Mfg. Co.*, 289 U.S. 334, 338 (1933) (“Where an important public interest would be prejudiced, the reasons for denying the injunction may be compelling.”) (citations omitted). In *Harrisonville*, the Supreme Court denied injunctive relief where it would cause potential health hazards, but “the injury to the company [was] wholly financial.” *Id.*

The alleged financial health of two online websites in this context does not merit risk to the nation’s pharmaceutical drug supply. Plaintiff cannot rely (without record citation) on whatever constraints the legal framework places on consumers to argue that removal of its sites from the NRL is in the public interest. Plaintiff’s request for a mandatory preliminary injunction against NABP should be denied for these reasons as well.

F. Plaintiff Cannot Clearly Show Likelihood of Success on Its Section 1 Claim.

Because of the foregoing, the Court need not even address Plaintiff’s likelihood of success on the merits. However, because Plaintiff cannot clearly show likelihood of success on the merits of its Section 1 claim, the Motion should be denied for this reason also.

To prevail, Plaintiff will have to establish four elements: (1) a violation of the antitrust law; (2) injury-in-fact to its business caused by the violation; (3) that it has antitrust standing – that it is an efficient enforcer of the antitrust laws; and (4) damages. *Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 105 (2d Cir. 2007); *Port Dock & Stone Corp. v.*

Oldcastle Ne., Inc., 507 F.3d 117, 121 (2d Cir. 2007). Even at this preliminary stage, at least two fatal defects in the Complaint are easily shown.¹¹

1. Plaintiff Cannot Establish Antitrust Injury.

In claims for both equitable relief and damages, an antitrust plaintiff must show that it has sustained an “antitrust injury,” which is (a) an injury of the type the antitrust laws were intended to prevent and (b) an injury that flows from that which makes defendants' acts unlawful. *Daniel*, 428 F.3d at 438. Plaintiff says this inquiry is “simple” because the “injuries to PharmacyChecker.com flow directly from the exclusion of PharmacyChecker.com from the market.” DE 33, 23. But Plaintiff is wrong that its injuries can be simply shown to be the result of its exclusion from this “market.”

PharmacyChecker.com is on NABP’s NRL because it links or refers patients to sites that facilitate the dispensing of prescription medications in violation of state or federal law. Catizone Decl., ¶33. Plaintiff charges a fee or earns revenue for these listings, and it is the loss of this revenue that Plaintiff contends is having a “disastrous effect” on its business. DE 19 (Cooperman Decl.), ¶¶ 11, 21.

These lost revenues from sponsoring foreign retail pharmacies Plaintiff asserts are its compensable injuries flowing from its exclusion from the market. But this claim of antitrust injury is fatally flawed. The Eighth Circuit has already concluded that harms resulting from the United State government’s restrictions on imports of pharmaceuticals is not the type of injury that the antitrust laws are designed to remedy. *Canadian Import*, 470 F. 3d at 790.

¹¹ Plaintiff also has not adequately pleaded either a product market or a geographic market, but for present purposes, discussing the lack of antitrust injury and allegations of conspiracy demonstrates the challenges Plaintiff will face in even surviving *Twombly/Iqbal*, let alone succeeding on the merits.

Canadian Import involved a claim by proposed classes of consumers who alleged that various manufacturers were conspiring to “suppress the importation of Canadian prescription drugs for personal use” in violation of the Sherman Act. *Id.* at 787. As Plaintiff alleges here, the consumers alleged that the manufacturers had created “blacklists” of pharmacies suspected of selling to U.S. consumers, among other things. *See id.* The Sherman Act claim was dismissed by the district court for lack of standing and that conclusion was affirmed. The court of appeals recognized that the class plaintiffs’ alleged injuries resulted from their “inability to import less expensive drugs distributed by Canadian pharmacies.” *Id.* at 792. However, because the U.S. “statutory and regulatory scheme” barred such imports (which continues in place today), the alleged conduct of the defendant manufactures “did not cause an injury of the type that the antitrust laws were designed to remedy.” *Id.* at 792 (citing *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998)) (municipality could not establish antitrust injury resulting from alleged pre-merger coordination between electric utilities that acted in accordance with regulatory scheme governing the utilities); *Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1111 (6th Cir. 1989) (foreign manufacturer could not establish antitrust injury from exclusion to US market where its products would infringe US patents); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 404 (2d Cir. 2005) (no antitrust injury where generic competition would only exist if there was illegal infringement of patent), *abrogated on other grounds F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013).

In short, Plaintiff’s claimed revenue loss is predicated on illegal conduct – importation of misbranded or adulterated pharmaceuticals in violation of federal law. *Canadian Import* and these other cases instruct that Plaintiff cannot be found to have any antitrust injury. The Court cannot find that Plaintiff has a “clear” and “substantial” probability that it will succeed in showing any violation of the Sherman Act.

2. Plaintiff Has Not Alleged An Agreement That Violates Section 1.

Additionally, or alternatively, Plaintiff does not have any likelihood of succeeding on its Sherman Act claim because the Complaint does not adequately allege a conspiracy in restraint of trade. Plaintiff's allegation that the defendants are part of a conspiracy to "restrain international price competition in the market for prescription medicine" must be tested under the *Twombly/Iqbal* framework.¹² DE 33 at 9. The allegations must be detailed enough to show that each claim is "plausible." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* An "entitlement to relief" requires "more than labels and conclusions Factual allegations must be enough to raise a right to relief above a speculative level." *Twombly*, 550 U.S. at 555.

Evaluating the plausibility of a complaint's allegations is a two-step process that is "context-specific" and "requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. First, a court should "identif[y] pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* Then, a court should "assume the[] veracity" of "well pleaded factual allegations" and "determine whether they plausibly give rise to an entitlement to relief." *Id.* "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* at 678. When considering plausibility, courts must also consider an "obvious alternative explanation" for defendant's behavior. *Id.* at 682.

Even at this preliminary stage, the defects in the allegations of NABP's involvement in

¹² In its prior memorandum, Plaintiff stated that the alleged conspiracy served to "restrain online pharmacies and wholly exclude international online pharmacy." DE 15-1, 9. Plaintiff's inconsistent description of the alleged conspiracy is one more reason why the Court cannot conclude that Plaintiff has a plain and obvious chance of ever proving an antitrust violation.

the purported conspiracy are apparent. Plaintiff's allegations as to NABP's involvement are either false or have obvious alternative explanations (or both).

Plaintiff alleges that sometime in 2008, NABP asked search engines to terminate their contracts with PharmacyChecker.com and that in February 2010, NABP and Google reached an agreement that Internet pharmacy advertisers must be certified by NABP's VIPPS program. DE 1, ¶¶69-70. However, NABP has no agreement with Google or any other search engine. Catizone Decl. ¶ 72. Rather, Google changed its advertising practices and chose to use NABP's VIPPS program following the 2009 DOJ investigation.¹³ NABP did not have any discussions with either DOJ or Google about Google's choice to use the VIPPS program. *Id.*, ¶ 76.

Plaintiff alleges that in April 2011, NABP and CSIP members held a meeting in Mt. Prospect about "cutting off websites that promote online international pharmacy sales." DE 1. However, members representing CSIP have never been to NABP offices. Catizone Decl., ¶ 74.

Plaintiff alleges that sometime in March 2012, NABP and ASOP held a "task force" meeting relating to international pharmacies at an unspecified location. DE 1, ¶¶65-66. In truth, this was an internal NABP meeting, the results of which were captured in a "Report of the Task Force on Internet Pharmacy Practice." Catizone Decl. ¶ 75, **Exh. K**. One representative of ASOP attended and provided information but did not participate in preparing the report. *Id.*

Plaintiff also alleges that NABP, among others, proposed the creation of a ".pharmacy extension." DE 1, ¶71. Yet, as a matter of common sense, the formation of a pharmacy-related domain name has a multitude of benefits for the industry as a whole and cannot be evidence of a conspiracy directed at Plaintiff.

Aside from these demonstrably false allegations, the balance of Plaintiff's complaint

¹³ See Olszowka Decl. Exh. P (DOJ press release).

relies on the NABP's wholly independent conduct which, by definition, cannot be evidence of a conspiracy. DE 1, ¶¶76(b), (g), and (h); ¶¶78-82. These allegations are hardly evidence of a conspiratorial "agreement" to do something unlawful. On the contrary, these allegations deal with unilateral conduct wholly unconnected to any other defendant.

Given the flat-out inaccuracies and alternative explanations of the alleged conspiratorial conduct, the Complaint does not pass the *Twombly/Iqbal* test. Certainly, the Court cannot find that plaintiff has a "clear" and "substantial" probability of establishing the alleged conspiracy.

V. PLAINTIFF SHOULD BE REQUIRED TO POST A BOND

The Court's Show Cause Order provides that no bond would be required. DE 16. Should the Court grant Plaintiff's Motion, (which it should not), this provision should be stricken and Plaintiff should be directed to post security. Under Fed. R. Civ. P. 65(c), a preliminary injunction become effectives only upon the applicant's posting of an amount that the district court determines to be adequate. *See Corning Inc. v. PicVue Electronics, Ltd.*, 365 F.3d 156, 158 (2d Cir 2004).

Although a district court has discretion in determining the "adequate" amount, it is error for the court to grant injunctive relief without making this determination. *See Corning*, 365 F.3d at 158. Plaintiff makes no mention of these requirements in its Brief. However, an order requiring NABP to reconfigure its Not Recommended List and notify third parties will have direct costs on its operations, reputational damage, and more importantly, costs to the public interest in the limiting the entry of misbranded or adulterated pharmaceutical products to the market. Although these costs are difficult to determine with precision, they should be considered, and a bond should be set in an amount to account for them.

VI. CONCLUSION

NABP respectfully requests the Court deny Plaintiff's Motion.

Dated: August 30, 2019

Respectfully submitted,

BARNES & THORNBURG LLP

/s/Paul Olszowka

Paul Olszowka, Esquire
One North Wacker Drive
Suite 4400
Chicago, IL 60606-2833
Tel: (312) 357-1313
Fax: (312) 759-5646
Email: paul.olszowka@btlaw.com

*Attorneys for Defendant National Association
of Boards of Pharmacy*

CERTIFICATE OF SERVICE

I, Paul Olszowka, hereby certify that on this 30th day of August, 2019, I caused a copy of Defendant National Association of Boards of Pharmacy's Brief in Opposition to Plaintiffs' Notice of Motion and Motion for Preliminary Injunction be served upon counsel of record via the Court's electronic filing system.

/s/Paul Olszowka